Translation

PCT/FR2003/002643

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SSL0096/PM	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/FR2003/002643	International filing date (*day/month/year*) 04 septembre 2003 (04.09.2003)	Priority date (*day/month/year*) 06 septembre 2002 (06.09.2002)
International Patent Classification (IPC) or national classification and IPC A61K 6/033		
Applicant DENTSPLY INTERNATIONAL INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 26 mars 2003 (26.03.2003)	Date of completion of this report 02 September 2005 (02.09.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR2003/002643

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1-15, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:
pages 1-26, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the drawings:
pages 1/1, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-8, 11-15, 17-19, 24-26	YES
	Claims	9	NO
Inventive step (IS)	Claims	15, 17-19, 24-26	YES
	Claims	1-9, 11-14	NO
Industrial applicability (IA)	Claims	1-9, 11-15, 17-19, 24-26	YES
	Claims		NO

2. Citations and explanations

The following documents are cited in the present report:

D1: WO 01/05797

D2: DATABASE WPI Section Ch, Week 198017 Derwent Publications Ltd., London, GB; Class B06, AN 1980-30039C XP002272820 & JP 55 035015 A (TOYO SEIYAKU KASEI KK), 11 March 1980 (1980-03-11)

D3: US-A-4 601 898

1. D1 relates to compounds identical to those on which the present application is based. Furthermore, D1 discloses compositions (see the examples of formulations for toothpaste (2 formulations) and mouthwash (2 formulations); all these examples comprise the compound of formula (III)).

1.1 The compounds according to D1 are intended for forming an amorphous protective layer (glaze).

The subject matter of claims 9 and 11 is therefore anticipated by D1 and fails to comply with the criterion of novelty as defined by PCT Article 33(2).

1.2 In so far as the formulations according to D1 have a pH from 6.5 to 7.5, they cannot anticipate the

subject matter of present claims 1 to 8 and 12 to 14.

The applicant confirms having disclosed that, at such pH values, said compositions enable titanium to be substituted for calcium atoms present in the apatite and fluorine to be substituted for hydroxyl groups, bicarbonates or impurities present in the apatite.

Despite being invited to do so, the applicant has omitted to submit the experimental results obtained that led to this conclusion. The applicant has not provided the results obtained for two otherwise identical formulations that only differ in their pH, one having a pH of 6.5 to 7.5 (therefore according to the teaching of D1) and the other having a pH less than 6 (therefore according to the wording of claim 1).

In the absence of such results, the examiner cannot concur with the applicant's assertion and therefore concludes that the subject matter of present claims 1 and 12 only differs from the formulations and the use made thereof according to D1 in the pH value, which is more acid, without said difference resulting in an effect with regard to the problem in question (strengthening apatite-based materials). For a person skilled in the art, modifying a formulation without modifying the useful properties thereof (i.e. with regard to the problem for which a solution is sought) does not constitute a difficulty and such a modification is devoid of an inventive step within the meaning of PCT Article 33(3).

Although claims 2, 3, 5 to 8 and 12 to 14 relate to technical features other than the pH value, the

above objection also applies to the subject matter of said claims, since the contribution of said features to solving the technical problem is identical, i.e. not established and/or not identified, and therefore no more determinant.

1.3 Since D1 does not relate to the use of compounds having formula (I) or of a composition including said compound having formula (I) for controlling the staining of apatite-based materials, the subject matter of claims 15, 17 to 19 and 24 to 26 is not only novel but also inventive within the meaning of PCT Article 33(2) and (3), having regard to D1.

2. D2 relates to compositions including a $TiF_4(F_2M)$ mixed salt, where M is an alkaline-earth ion or two alkaline ions. Said compositions enable caries to be controlled, as do those of D1, D3 and the present application. The applicant uses the words "strengthening apatite-based materials" to describe this effect.

The subject matter of claim 4 does not relate to anything else. In so far as the pH of the compositions according to D2 is not specified, said document cannot be cited under the terms of PCT Article 33(2), but can under the terms of PCT Article 33(3), above all with regard to the subject matter of claim 4, which cannot be considered inventive.

3. D3 relates to aqueous compositions having a pH of 3.5 to 5.5 (see column 2, lines 46 to 53) that include a TiF_4 complex, a chelating agent such as salicylic acid (ligand (IV) in the present application) and 2,4- and 2,6-dihydroxybenzoic acids.

Since the formulations of the examples contain no such chelating agents, novelty is acknowledged.

However, inventive step is denied for the subject matter of claims 1 to 3, 5 to 9 and 11 to 14 on the basis of the arguments set forth in the discussion of D1.

4. The examiner is of the opinion that only the subject matter of claims 15 (and therefore additionally 17 to 19) and 24 (and therefore additionally 25 and 26) meets PCT requirements. Said subject matter aims to protect apatite-based materials against staining, which is not the subject of any of the documents cited in the international search report.

That being so, the unity of the above-mentioned claims is established.

Observations

Claims 20 to 23 are not supported by the description. When any examination takes place in the regional phase, the claims the applicant wishes to submit should be made self-consistent in respect of TiF_4, which, depending on the claim in question, is or is not taken into consideration.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III

The subject matter of claims 10, 16, 20, 21, 22 and 23 is not clear.

1. Claim 10 relates to a use according to claim 9. However, no mention is made of a composition anywhere in said claim 9, but rather a use of a compound having formula (I) for strengthening apatite-based materials.

2. Claims 16, 20, 21, 22 and 23 relate to a use according to claim 15. However, no mention is made of a composition anywhere in said claim 15, but rather a use of a compound having formula (I) as an anti-stain agent for apatite-based materials.

3. Examination under the terms of PCT Chapter II offers little scope for views to be exchanged between the examiner and the applicant. The examiner has nevertheless striven to provide certain elements of assessment, which the applicant should be able to use at the time of entry into the regional phase.

4. The scope of claim 10 should be brought closer to either that of claim 9 or that of claim 12. Any objection raised against either of these claims will therefore apply to claim 10.

5. The scope of claims 16, 20, 21, 22 and 23 should be brought closer to either that of claim 15 or that of claim 24. Any objection raised against one of these claims will therefore apply to claims 16, 20, 21, 22 and 23.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III

6. The applicant should ensure that there are no redundant claims, whether independent or not. Certain patent offices (such as the EPO), may raise objections to redundant independent claims at the time of entry into the regional phase.

7. The examiner confirms the opinion of the International Preliminary Examining Authority that a method for treating the body of a human or an animal is claimed (*inter alia*). In so far as said method (treatment of dental caries) is, at any event, neither novel nor inventive (see below), whereas a method for preventing the staining of apatite-based materials is both novel and inventive, yet cannot be considered to be a therapeutic treatment (but rather a cosmetic treatment), it is not necessary to develop this point at the present stage.